LEARNING UDI COMMUNITY

AHRMM
Advancing Health Care through Supply Chain Excellence

LEARNING UDI COMMUNITY (LUC): RESOURCES AND DELIVERABLES

Learning UDI Community

WWW.AHRMM.ORG/LUC

LUC RESOURCES AND DELIVERABLES

About AHRMM:

The Association for Health Care Resource and Materials Management (AHRMM) is a professional membership group of the American Hospital Association (AHA) with more than 4,300 members representing the entire health care supply chain, including hospitals, manufacturers, distributors, group purchasing organizations, and health technology vendors.

The Learning UDI Community:

AHRMM's Learning UDI Community (LUC) is a health care collaborative effort founded in 2013, in partnership with the U.S. Food and Drug Administration's Center for Devices and Radiological Health, to address issues impacting the adoption and implementation of the Unique Device Identifier by developing a common understanding and approach within the health care setting.

AHRMM and the U.S. FDA have a shared interest in facilitating the successful adoption of Unique Device Identifiers (UDIs) across the health care device ecosystem, especially with regard to the initial capture of UDI in supply chain and clinical health information technology (IT) systems, as both organizations strongly believe the Unique Device Identifier should be the single unifying way to track medical devices across the entire healthcare value chain, from point of manufacture through, use, and, in the case of implantable devices, through the lifecycle of that product.

Since its founding, the LUC has received national and international recognition for the success of its collaborative model—establishing a consistent platform where stakeholders come together from across the health care ecosystem to address and resolve UDI adoption challenges.

The Learning UDI Community is not an advisory committee to the U.S. FDA, nor should it be used as a direct sales opportunity. Participants are respectfully asked not to abuse their involvement nor knowledge gained through the LUC for overt sales activities.

LUC Work Groups:

LUC work groups are comprised of a diverse group of health care supply chain professionals, who work together to develop progressive practices, proposed solutions, and resources to focus on topics that can accelerate UDI adoption.

The findings and recommendations of the work groups are designed to benefit the health care field by providing a more consistent, consensus-based processes to support UDI adoption. You do not need to be an AHRMM member to join the community or access any of the work group deliverables. Join the LUC at www.ahrmm.org/LUC.

Work group deliverables include best recommended practices, case studies, and power point content templates, with the goal of promoting and accelerating UDI adoption. These progressive practices are shared through the Learning UDI Repository.

Available LUC Resources and Deliverables

UDI Capture Case Studies

The UDI Capture Work Group released new case studies describing how two health care organizations are adopting and implementing device identifiers (DIs). The case studies are intended to serve as examples of best practices that can be reproduced in other health care organizations to accelerate the adoption of the UDI. Click on each link to read the case study:

1. Baptist Health https://bit.ly/2vBLZk6
2. Beaver Dam Community Hospital https://bit.ly/2KWV1fY
3. Eskenazi Health https://bit.ly/2MSOsLU
4. FMOLHS: Use of DI for Product Identification at the Point of Use in the OR https://bit.ly/2ucvqly
5. FMOLHS: Automation of Product Data Capture in the EHR https://bit.ly/2KZcNyQ
6. Stanford Health Care https://bit.ly/2KTEIZK
7. University Health Network https://bit.ly/2m0nJSh
8. University of Tennessee Medical Center https://bit.ly/2KNMyi7

Unit of Use Report and Webcast Series

Three-part webcast series about the FDA Unique Device Identification (UDI) Unit of Use (UOU).

1. Part One: The FDA UOU Explained (Webcast) https://bit.ly/2KVKykX
2. Talking points and PowerPoint presentation (PDF) https://bit.ly/2ucvXu2

1. Part Two: Clinical Recognition of the UOU (Webcast) https://bit.ly/2J0c7rt
2. Talking points and PowerPoint presentation (PDF) https://bit.ly/2MSPEyS

1. Part Three: Potential UOU Examples (Webcast) https://bit.ly/2zh2PYp
2. Talking points and PowerPoint presentation (PDF) https://bit.ly/2tWFPZJ

LUC RESOURCES AND DELIVERABLES

Clinically Relevant Size (CRS) Workgroup Report

The Clinically Relevant Size work group was convened to examine the utility of device size data in the FDA GUDID system, provides a framework to facilitate correction of existing device size data in the GUDID, and standardize the accurate capture of device size data for new entries into the GUDID.

Report of the GUDID Clinically Relevant Size (CRS) Work Group https://bit.ly/2KFKbPh

Catalog Number Work Group Report

Catalog Number work group provides the business case and field value for inclusion of Catalog Number in Global Unique Device Identification Database (GUDID) Device Identifier submissions to drive compliance and adoption within the field.

Catalog Number Work Group Report https://bit.ly/2NvYfss

Low Unit of Measure (LUM) UDI Single Device Work Group Report

This document serves as a guide for supply chain partners to begin a dialogue to ensure that medical devices comply with FDA's Unique Device Identification (UDI) requirements as well as meet the FDA's goal of enhancing patient safety. Low Unit of Measure (LUM) programs are complex and the steps outlined in this best practices document are a critical first step.

Low Unit of Measure (LUM) UDI Single Device Work Group Report Supply Chain Best Practices: LUM and UDI Implementation https://bit.ly/2EVc1jv

Business Case for the UDI Benefits to Health Care Report and Presentation

1. Comprehensive Report detailing typical process flows, UDI adoption for tasks within those process flows, and future proposed typical process flows.

https://bit.ly/2m1u9R8

Five areas were covered in this report:

- Inventory Management
- Recalls
- Adverse Events
- EHR integration to Registries

- Specialty Inventory ("trunk stock")

2. Comprehensive Presentation https://bit.ly/2tZU9jZ

HCTP (Human Cellular Tissue Products) Report and Presentation

Depending on the type of processing, or manipulation of the HCT/Ps, the HCT/Ps can be considered a drug, a medical device, or a biological. The intention of the HCTP report is to provide information on HCT/Ps, HCT/Ps regulation as a medical device, traceability of HCT/Ps, and the US Food and Drug Administration (FDA) Unique Device Identification (UDI) Rule and its effects on HCT/Ps regulated as a medical device.

UDI Guidance document for medical devices containing HCT/P Report https://bit.ly/2uds5sG

UDI Guidance document for medical devices containing HCT/P Presentation https://bit.ly/2NyJrZZ

External UDI Content and Deliverables to Date

1. Building UDI into Longitudinal Data for Medical Device Evaluation (The BUILD Initiative) https://bit.ly/2NtppA2
2. FDA AccessGUDID https://bit.ly/2mXdFf6
3. FMOLHS-GS1 US Data Standards Master Process Implementation Plan https://bit.ly/2lXJ928
4. General UDI and Health Care Data Standards Information https://bit.ly/2MYc81A
5. Medical Device Epidemiology Network Initiative (MDEpiNet) https://bit.ly/2MUNOgJ
6. Registry Assessment of Peripheral Interventional Devices (RAPID Initiative) https://bit.ly/2m1uyTE
7. Report of the MDEpiNet AUDI Workgroup https://bit.ly/2NwtX8T

Alternative Names for the Device Identifier of the UDI used by each Issuing Agency

8. GS1 – Global Trade Identification Number https://bit.ly/2u0Ut26
9. HIBCC Universal Product Number https://bit.ly/2m1uP98
10. ICCBBA Processor Product Identification Code (PPIC) https://bit.ly/2lYAWuI

LUC Resources and Deliverables in Development

Data Quality Initiative White Paper Series

This is a multi-part series with content derived from our four data quality workshops held last year with both provider and supplier stakeholder groups. The reports will highlight the challenges as well as the recommended practices these stakeholder groups have identified. The goal is to ensure that the data in the GUDID is valuable to all end-users as providers access this information to augment their ERP systems and processes, clinical documentation within EHRs, and patient/consumer access to product information, fulfilling the intent that the GUDID is the source of truth for the device identifier.

Business Case for the UDI – Executive Summary

Condensing the comprehensive report and presentation into an executive summary template for health care supply chain and clinical professionals to use when presenting to senior leadership on the value and benefits of the UDI.

Barcodes at the Point of Care

In various field forums and in the course of deploying UDI in Operating Rooms, Cath Labs, etc., multiple barcodes provided on product packaging makes it "difficult" for clinicians to locate and scan and the UDI barcode. This work group, comprised of providers and manufacturers, will explore whether we can align on a standard or set of standards on barcode/2D matrix placement, and the collaborative development of recommended practices to minimize multiple barcodes.

Multiple Device Identifiers

The objective of the UDI system is to create assignment of Unique Device Identifiers to medical devices. The expectation is that a given version/model of a given device would have only one Device Identifier (DI), however multiple DI's have been assigned for a given version/model of a device as evidenced through conversations with UDI Capture case studies participants and the Data Quality Initiative. This is introducing challenges for health care organizations that import and use data from Global Unique Device Identification Database (GUDID) into their ERP and EHR systems. This work group, comprised of providers and manufacturers, are working together to establish a clear understanding of when a new DI should be allowed for a device with the goal of moving towards the best practice of a 1:1 relationship between the DI and the manufacturers catalog number (version/model).

Device Categorization

Device categorization is a data element that allows for analysis of device behavior at a higher level than that provided by a device identifier, company name or brand name. It provides the ability to search across a device type or category (containing like

devices) to see trends or signals you could not otherwise see. Work group membership includes medical device manufacturer and FDA representatives as well as health policy consultants and the co-chairs who represented GMDN, health systems, and SNOMED.

High Risk Implants

The High Risk Implant work group is charged with developing a set of search criteria, using the FDA's definition of an implantable device, which correctly identifies implantable medical devices. These criteria could be used in multiple ways to support documentation of implants in health IT (ERPs, EHRs) and included in insurance claims. UDI adoption efforts are aimed at linking the UDI of implantable devices to the patients who have received those devices at the point of implant, and to document one or both portions (DI and PI) of the UDI in health IT systems. These efforts will support collection of real-world data (RWD).